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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/516,194      | 03/01/2000  | LETTS L GORDON       |                     | 3420             |

25270 7590 01/13/2005

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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT PAPER NUMBER

1626

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

## Application No.

09/516,194

## Applicant(s)

GORDON ET AL.

## Examiner

Laura L. Stockton, Ph.D.

## Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2-8, 10-17, 19-31, 33-40, 104-106 and 116 is/are pending in the application.
- 4a) Of the above claim(s) 4-8, 10-17, 19-31, 33-40 and 104-106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 3 and 116 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/13/2000 + 4/11/2000
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

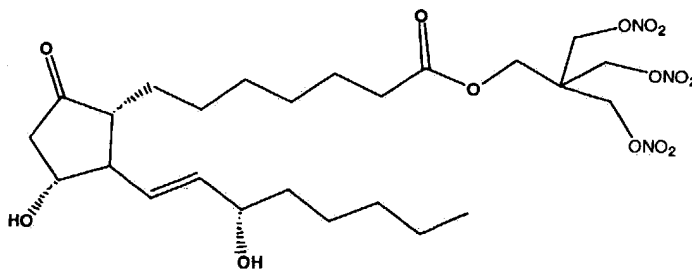
Claims 2-8, 10-17, 19-31, 33-40, 104-106 and 116 are pending in the application.

### *Election/Restriction*

Applicants' election with traverse of Group II (reproduced below), and the species of Example 11 (reproduced below) on pages 52-54 of the instant specification, in the reply filed on October 15, 2004 is acknowledged.

- II. Claims 2, 3 and 116, drawn to compounds of formula (I) wherein  $R_1$  and  $R_2$  taken together are  $=CH_2$  or  $=O$ ; one of  $R_3$ ,  $R_4$ ,  $R_5$  or  $R_6$  is  $OD_1$  (wherein  $D_1$  is hydrogen or D; and D is Q) and  $R_7$  is  $OD_1$  (wherein  $D_1$  is hydrogen or D; and D is Q); A is  $-CH=$  or  $CH_2$ ; B is  $-CH=$  or  $CH_2$ ; Z is (a), (b), (c) or (h); X is  $COOR_{11}$  (wherein  $R_{11}$  is  $D_1$ ;  $D_1$  is hydrogen or D; and D is Q or K), classified in class 560, subclass 121.

### Example 11



The traversal is on the ground(s) that: (1) the restriction requirement is improper; (2) the previous Examiner had allowed certain claims to the extent that the claims were readable on the elected species; (3) Applicants filed a Petition dated April 18, 2002 requesting reconsideration and reversal of the Examiner's decision on the issue of misjoinder, which Petition was granted; and (4) the corresponding PCT application (PCT/US00/05286) does not set forth any lack of unity objection.

All of Applicants' arguments have been considered but have not been found persuasive. In the restriction requirement dated August 16, 2004, explanations were given why the various groups were considered patentably distinct. Further, it is an undue burden to the Examiner and the Patent Office's resources to examine the instant application in its entirety. The instant claims embrace much more patentably distinct subject matter than just the elected species of Example 11. Also, noted is the various provisos in independent claim 2.

At present, the entire scope of elected Group II has been examined, not just the elected species of Example 11. Additionally, an Examiner in the national phase is not bound by the decision made by the international Examiner in not indicating that the claims lack unity of invention.

Further, the Petition and the decision on the Petition has also been noted. However, in accordance with M.P.E.P. §821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

The requirement is still deemed proper and is therefore made  
FINAL.

Subject matter not embraced by elected Group II and claims 4-8,  
10-17, 19-31, 33-40 and 104-106 are withdrawn from further  
consideration pursuant to 37 CFR 1.142(b), as being drawn to  
nonelected inventions. Applicant timely traversed the restriction  
(election) requirement in the reply filed on October 15, 2004.

It is suggested that in order to advance prosecution, the non-elected  
subject matter be canceled when responding to this Office Action.

***Claim Rejections – 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C.

112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 116 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the prostaglandins found on page 16, line 32 through page 17, lines 5, does not reasonably provide enablement for all prostaglandins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,

5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case, Applicants are claiming all prostaglandins having at least one NO group. The nature of the pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. Therefore, one skilled in the art cannot practice the instant invention without undue experimentation. Hence, the broad terminology "prostaglandin comprising at least one NO group" is not enabled.



The following is a quotation of the second paragraph of 35 U.S.C.

112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 2, under the definition of  $R_e$  and  $R_f$ ,  $R_e$  and  $R_f$  are being used to define  $R_e$  and  $R_f$  (e.g.,  $-C(R_e)(R_f)_k-T-Q$ ).

### *Claim Rejections - 35 USC § 103*

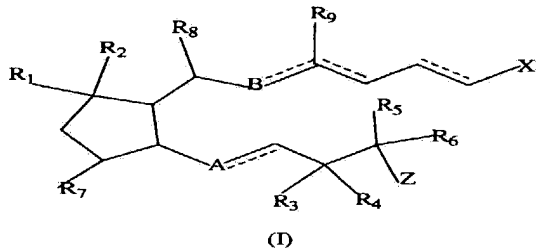
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

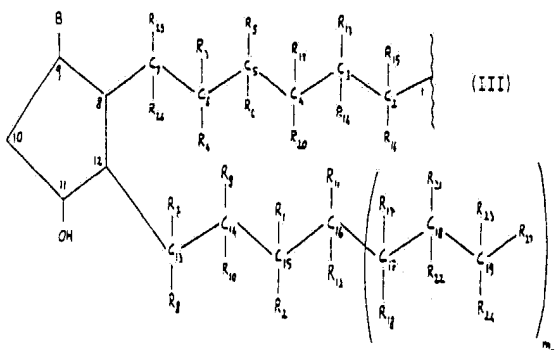
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Del Soldato {WO 98/58910}.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Applicants claim nitrostates and nitrosylated prostaglandins. Del Soldato (pages 3-9) teaches nitrosylated prostaglandins that are structurally similar to the instant claimed compounds. See, for example, the table below.

| Applicants' compounds   | Del Soldato's compounds                   |
|---|---|
| Formula (I)<br><br>(I) | formula (I) on page 3<br>$A - X_1 - NO_2$ |

|  |  |
|--|--|
| <p>X is <math>-\text{COOR}_{11}</math>;<br/> <math>R_{11}</math> is <math>D_1</math>;<br/> <math>D_1</math> is D;<br/> D is K;<br/> <del><math>K</math> is <math>-\text{W}_2-\text{E}_3-(\text{CR}_6\text{R}_7)_p-\text{E}_7-(\text{CR}_6\text{R}_7)_x-\text{W}_2-(\text{CR}_6\text{R}_7)_y-\text{W}_2-\text{E}_7-\text{W}_2-(\text{CR}_6\text{R}_7)_z-\text{T}-\text{Q}</math>;</del><br/> Which is <math>-\text{CH}_2-(\text{COOH})\text{Phenyl}-\text{CH}_2-\text{ONO}_2</math></p> | <p>A = formula (II) - page 3<br/> <math>\text{R}(\text{CR}_a\text{R}_b\text{O})_u(\text{COX})_t</math><br/> u is zero;<br/> t is 1;<br/> X = O;<br/> <math>X_1</math> is <math>-\text{CH}_2-(\text{COOH})\text{Phenyl}-\text{CH}_2\text{O}</math></p>  |
| <p>B is <math>-\text{CH}_2-</math>;<br/> <math>R_8</math> and <math>R_9</math> are each hydrogen;<br/> A is <math>-\text{CH}=\text{}</math><br/> <math>R_3</math> is <math>-\text{OD}_1</math><br/> <math>D_1</math> is hydrogen<br/> <math>R_4</math>, <math>R_5</math> and <math>R_6</math> are each hydrogen<br/> Z is butyl</p>  | <p>R is formula (III)</p>  <p>there is a double bond between <math>\text{C}_{13}-\text{C}_{14}</math> (pages 4 and 7);<br/> <math>m_0</math> is 1 (page 4);<br/> <math>R_2</math> is OH;<br/> <math>R_{27}</math> is <math>\text{CH}_3</math> (page 7);<br/> All remaining R variables are either absent because of a double bond or represent hydrogen</p> |
| <p><math>R_1</math> and <math>R_2</math> taken together is <math>=\text{O}_2</math>;<br/> <math>R_7</math> is <math>\text{OD}_1</math><br/> <math>D_1</math> is hydrogen;</p>  | <p>B is <math>=\text{O}</math> (pages 5 and 7)</p>   |
|  | <p>or see Example 1 on page 14</p>   |

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

*Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)*

The indiscriminate selection of “some” among “many” is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating impotence).

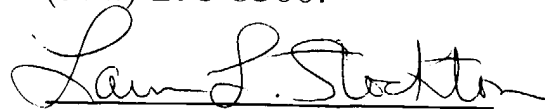
One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating impotence. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of *prima facie* obviousness has been established.

The elected species of Example 11 is allowable over the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



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Art Unit 1626, Group 1620  
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January 10, 2005